K103262

APR - 5 2011

510(k) SUMMARY
(Per 21 CFR 807.92)

General Company Information

Name: Tornier, Inc.
Contact: Lael J. Pickett
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Tornier, Inc.

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Date Prepared March 14, 2011

General Device Information

Product Name: 3.4mm QuickDraw™ Convertible Fixation Implant

Classification: "Non-degradable soft tissue fixation fastener"
Product code: MBI - Class II

Regulation: 21 CFR 888.3040
Smooth or threaded metallic bone fixation fastener

Predicate Device

Smith & Nephew, Inc. Bioraptor™ 2.3 PK Suture Anchor.
[510(k) Number K071586]

ArthroCare, Inc.. LabraLock P™ Knotless Fixation Device
Suture Anchors
[510(k) K061349]

K103262

Description

The Implant system includes a 3.4mm diameter PEEK (polyether-etherketone) bone anchor, pre-mounted on a disposable inserter. The anchor is preloaded with USP size 2 Ultra High Molecular Weight Polyethylene suture, and a threading device. The device is designed to be inserted into a pre-drilled hole using a reusable drill guide. The anchor may be used as a tied implant, or it can be converted to a knotless fixation device by following the instructions for use. Thus, the QuickDraw™ Convertible Fixation Implant allows the user to select between tied or knotless fixation.

Intended Use (Indications)

The Tornier, 3.4mm QuickDraw™ Fixation Implant is intended for use in arthroscopic or mini-open surgical procedures either as a standard bone anchor or as a knotless system for fixation of soft tissue to bone.

The QuickDraw™ Implant is intended for use in the following applications:

Shoulder: Rotator Cuff Repair, Bankart Repair, Anterior Shoulder Stabilization, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulabral Reconstruction
Foot/Ankle: Lateral or Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair, Bunionectomy
Elbow, Wrist and Hand: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction, Lateral Epicondylitis Repair
Knee: Extra-capsular Repairs, Patellar Realignment and Tendon Repairs, Iliotibial Band Tenodesis

Substantial Equivalence

This submission supports the position that the Tornier QuickDraw™ 3.4mm Fixation Implant System is substantially equivalent to previously cleared devices, including those listed above. Data have been provided in the submission that demonstrates that in both the traditional knotted suture and knotless configurations the anchor pull-out forces are equivalent or superior to referenced predicate devices. The referenced predicate devices list the same range of clinical uses.

Conclusions

Tornier, Inc. believes that the information provided establishes that similar legally marketed devices have been used for the same clinical applications as the Tornier QuickDraw™ Fixation Implant System. The materials from which the Tornier device is fabricated have an established history of use, and the devices have been tested in accordance with applicable FDA guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Tornier, Inc.
% Ms. Lael J. Pickett
Director Regulatory and Clinical Affairs
100 Cummings Center, Suite 444C
Beverly, Massachusetts 01915

APR - 5 2011

Re: K103262
Trade/Device Name: 3.4mm QuickDraw™ Convertible Fixation Implant
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: March 14, 2011
Received: March 16, 2011

Dear Ms. Pickett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K103262

Device Name: 3.4mm QuickDraw™ Convertible Fixation Implant

Indications For Use:

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Prescription Use ____X____	**AND/OR**	**Over-The-Counter Use _____**
(Part 21 CFR 801 Subpart D)		**(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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